

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Serc 16mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg betahistine dihydrochloride.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from UK*

Round, biconvex, scored, white to almost white tablets imprinted '267' on one face. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA2010/016/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2010/016/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose  
Mannitol (E421)  
Citric acid monohydrate  
Colloidal anhydrous silica  
Talc

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

The shelf –life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin

#### **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in the original package.

#### **6.5 Nature and contents of container**

Blister strips of 21 tablets. The blister strips are made of PVC/PVDC film with a covering aluminium foil. Pack size 84 tablets

#### **6.6 Special precautions for disposal and other handling**

No special requirements

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Primecrown 2010 Limited  
4/5 Northolt Trading Estate  
Belvue Road  
Northolt  
Middlesex UB5 5QS  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1633/026/002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 8<sup>th</sup> February 2013

### **10 DATE OF REVISION OF THE TEXT**

January 2019